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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,021	08/06/2001	Yongming Sun	DEX-0150	7327
26259	7590	02/22/2005	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,021

Applicant(s)

SUN ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. The Amendment filed November 23, 2004 in response to the Office Action of July 23, 2004 is acknowledged and has been entered. Previously pending claim 1 has been amended. Claim 1 is currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claim 1 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth.

Applicant argues that US Patent 5,733,748 establishes that for colon specific genes, a correlation would be expected between polynucleotide and polypeptide and Applicant directs the Examiner to col 2, lines 36-42 of that patent where it is taught that an aspect of the present invention is to provide a method and products for diagnosing colon cancer metastases by detecting an altered level of a polypeptide corresponding to the colon specific genes of the present invention.

The argument has been considered but has not been found persuasive because although the patent teaches diagnosis of colon cancer metastases by detecting an altered level of a polypeptide corresponding to the colon specific gene of that invention, the cited reference in the patent does not teach the correlation between overexpression of mRNA and polypeptide, the cited reference only teaches that the expressed polypeptide can be used for diagnosis. For the reasons previously set forth, this does not enable the claimed invention.

Applicant further argues that at col 8, lines 16-19 the '748 patent teaches that "it is detection of this enhanced transcription or enhanced protein expression in cells other than those derived from the colon, which is indicative of metastasis

of colon cancer. The argument has been considered but has not been found persuasive because contrary to Applicant's arguments, the cited reference does establish that for colon specific genes, a correlation would be expected between polynucleotide and polypeptide expression, but rather specifically teaches the detection of enhanced transcription or enhanced protein expression. This does not indicate that there is a correlation between overexpression of mRNA and polypeptide.

Applicant further argues that US Patent 5,861,494 also teaches that altered levels of polypeptide corresponding to a colon specific gene indicated a colon cancer diagnosis and specifically points to col 8, lines 10-13 wherein it is taught that elevated levels of colon specific polypeptides of the present invention indicates active transcription and expression of the corresponding colon specific gene product. The argument has been considered but has not been found persuasive because altered levels of polypeptide corresponding to a colon specific gene and diagnosis thereby does not, for the reasons previously set forth, establish a correlation between mRNA and polypeptide overexpression. Further, although the '494 patent does state that elevated levels of colon specific polypeptides of the present invention indicates active transcription and expression of the corresponding colon specific gene product, the instant specification does not teach that the polypeptide claimed is expressed differentially between normal and colon cancer patients. Further, although the '494 patent indicates active transcription and expression of the corresponding colon specific gene product, it does not teach that the gene product is overexpressed or teach a predictable correlation between overexpression of mRNA and overexpression of polypeptide. It teaches only that the mRNA is actively transcribed.

Applicant further argues that the claimed invention for detecting the presence of colon cancer is not dependent on the subcellular location of the protein. The argument has been considered but has not been found persuasive because the claimed method is drawn to *in vivo* imaging which the specification specifically teaches includes the use of antibodies against CSG *in vivo*. No other method of *in vivo* imaging is taught or contemplated. Given that antibodies are large molecules that bind to cell surface in imaging assays, it is apparent that the cellular location of the claimed CSG is critical to the enablement of the claimed invention.

Applicant further argues that successful detection methods have been developed for cell surface receptor proteins as well as secreted proteins and thus there is no reason for one of skill to doubt the teachings of the instant specification regarding successful use of the claimed method for detecting the presence of colon cancer. The argument has been considered but has not been found persuasive because neither the specification nor the art of record teaches that the claimed CSG is a secreted protein.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE

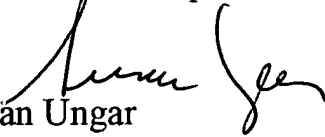
SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
February 17, 2005